Kindly amend claim 22 by replacing the number "11" with –1--, and the word "agent" with –polypeptide--.

Kindly amend claim 23 by replacing the number "11" with –1--, and the word "agent" with –polypeptide--.

Kindly amend claim 24 by replacing the number "11" with –1--, and the word "agent" with –polypeptide--.

REMARKS

This communication is reply to the Examiner's communication mailed August 13, 2000 in which claims 1-24 were made subject to a restriction requirement, alleging four inventions and describing them as follows:

Group I: Claims 1-5 & 10, drawn to methods for extension the effective time period tissue is paralyzed with a clostridial toxin comprising administering a binding agent/competitive inhibitor that prevents the regenerative activity of various neurotrophic factors;

Group II: Claims 1-8, to methods for extension the effective time period tissue is paralyzed with a clostridial toxin comprising administering an antibody agent/competitive inhibitor that binds various neurotrophic factors;

Group III: Claims 1-6, 9, 11, and 13-24, drawn to methods for extension the effective time period tissue is paralyzed with a clostridial toxin comprising administering agents that prevent the expression of various neurotrophic factor genes, and

Group IV: Claim 12, drawn to methods for stimulating the outgrowth of neural sprouts from damaged neural tissue comprising contacting the tissue with a composition comprising active domains of various neurotrophic factors.

Applicants elect to prosecute Examiner's restriction Group III (claims 1-6, 9, 11, and 13-24).

Traversal of Restriction Requirement

Applicants respectfully traverse the restriction requirement with respect to claims 1-11 and 13-24 (Groups I -III). The restriction with regard to Group IV (claim 12) is not contested.

The invention of Groups I-III is a method for extending the effective time period tissue is

paralyzed with a clostridial toxin. As indicated in claim 1 and further disclosed in the specification, the manner in which this is accomplished is by inhibiting the neuroregenerative activity of an indicated neurotrophic polypeptide, so as to inhibit neural sprouting in such treated tissue. Claims 2-11 and 13-24 all depend directly or indirectly from claim 1.

Applicants traverse the restriction requirement as it relates to claims 1-11 and 13-24 for the following reasons. First, these claims are not distinct. In order to be distinct, the claimed invention must be capable of separate manufacture, use or sale. M.P.E.P. §802.01. The claims in question are method claims; a method is clearly not manufactured or sold. Moreover, to say that different embodiments of the same method (i.e., a single independent claim and a set of claims dependent thereupon) are "capable of separate use" does not make sense. A method is a use of at least one article or item of information. As such, a single method necessarily excludes other methods using (uses of) the same article or item. Thus, claims 1-11 and 13-14 are not distinct.

Furthermore, even assuming for the sake of argument that the indicated claims were distinct, the Examiner has not adequately shown that there would be a serious burden if the claims are not restricted. The Examiner has indicated different classifications for each of Groups I-IV. However, in order to establish that claims define inventions having a separate classification in the art, M.P.E.P. §808.02 requires that "the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation . . . (A) . . . that each distinct subject has attained recognition in the art as a separate subject for inventive effort and also a separate field of search." (Emphasis added). In this case not only has the Examiner not made the required *prima facie* showing by appropriate explanation, but such explanation cannot properly be made.

Each of claims 1-11 and 13-14 is drawn to a method for extending the effective time period tissue is paralyzed when treated with a clostridial toxin comprising inhibiting the neuroregenerative activity within the treated tissue, so as to inhibit neural sprouting in such tissue. While it is true that this is accomplished by inhibiting the expression or activity of a number of different intracellular neurotrophic factors, the method is clearly drawn to a single subject of inventive effort. Applicants believe that the classifications indicated by the Examiner are those defining various neurotropic factors. However, the present claims are not drawn to neurotropic factors, but rather to a unitary method for increasing the effectiveness of therapeutic neurotoxin treatment. The Examiner has provided no evidence that such a method

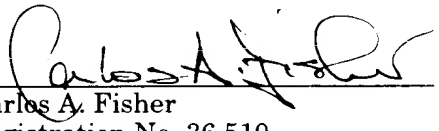
has attained recognition in the art at all, much less that the various embodiments of the method have been recognized as separate areas of inventive endeavor. Thus, there is simply no indication that serious hardship would occur if these claims were examined together.

CONCLUSION

For the reasons indicated above, Applicants respectfully urge the Examiner to reconsider and withdraw the Restriction Requirement as it pertains to claims 1-11 and 13-24. While no fee is thought to be required with regard to this communication, if Applicants are in error please use our Deposit Account 01-0885 for the payment of any fees that may be due.

Respectfully Submitted,

Date: Sept 26, 2000

Signature: 

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